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Filed : September 5, 2003

### REMARKS

Upon entry of the foregoing amendment, Claims 1-11, 44-51, 62, and 65-73 remain pending. Claims 12-43, 52-61, 63 and 64 have been canceled without prejudice to their further prosecution in a continuation application. New Claims 72 and 73 have been added.

#### Double Patenting

The Examiner objects to Claims 63-71 under 37 C.F.R. § 1.75 as being a substantial duplicate of Claims 1 and 3-10. Specifically, the Examiner states that "the only difference between Claim 63 (as it depends from Claim 62) and independent Claim 1 is that the term DK is replaced by the definition of DK, gas permeability (Specification, page 7, lines 3-5)." Further, the Examiner states that "therefore these terms have the exact same meaning, with a slight difference in wording and Claim 63 is a duplicate of Claim 1."

Applicants have canceled Claims 63 and 64 and respectfully submit that the remaining claims (i.e., Claims 65-71) are patentably distinct from Claims 1 and 3-10. Accordingly, Applicants respectfully request the withdrawal of this objection.

#### Objections to the Claims

The Examiner objected to Claim 64 because of the following informalities "in line 1, 'lens of claim 62' should be 'lens of claim 63' since there are no angled surfaces in claim 62, however, there is an angled surface in claim 63." Applicants have canceled Claim 64 and accordingly consider this objection to be moot.

#### Rejection of the Claims under 35 U.S.C. § 102

Claims 62 and 67-69 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Domschke et al. (U.S. Patent No. 6,043,328). Applicants have amended Claim 62.

Domschke et al. discloses a polysiloxane-polyol macromer material. See Domschke, col. 1, lines 6-10. Domschke also discloses "contact lenses which include a polymer according to the invention." Domschke, col. 17, lines 37-39. Also disclosed is a macromer or a polymer or cross-linked polymer prepared therefrom "for coating a base material, . . . preferably polymer substrates, for example products which can be used ophthalmically, such as contact lenses, . . . hydrophilic coatings being preferred." Domschke, col. 20, lines 12-22.

However, Domschke et al. does not disclose, among other things, a hybrid contact lens comprising a substantially rigid central portion having a gas permeability value of at least  $30 \times 10^{11}$  (cm<sup>2</sup>/sec) (mL O<sub>2</sub>) / (mL x mm Hg), and a substantially flexible annular hydrophilic portion

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coupled to the substantially rigid central portion at a junction defined at an outer edge of the substantially rigid central portion, as recited in amended Claim 62. Moreover, as discussed in the declarations referenced below, Domschke does not disclose a hybrid lens, as contemplated in the claims of the above-identified application. Accordingly, Applicants respectfully submit that amended Claim 62 is allowable over Domschke et al. Claims 67-69 depend from amended Claim 62 and would likewise be allowable over Domschke for at least the same reasons as amended Claim 62.

Rejection of the Claims under 35 U.S.C. § 103

Claims 1-11, 44-51, 63-66, and 70-71 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Domschke et al. in view of Sohnges (GB 1 417 650). Applicants have amended Claims 1 and 11. As noted above, Applicants have canceled Claims 63 and 64.

As discussed above, Domschke et al. discloses a polysiloxane-polyol macromer material and contact lenses that include this material. Additionally, Domschke also describes the use of a macromer or a polymer or cross-linked polymer prepared therefrom "for coating a base material, . . . preferably polymer substrates, for example products which can be used ophthalmically, such as contact lenses, . . . hydrophilic coatings being preferred." Domschke, col. 20, lines 12-22.

However, Domschke does not teach or suggest, alone or in combination with the cited references, a hybrid contact lens comprising a substantially rigid central portion having a DK value of at least  $30 \times 10^{-11}$  (cm<sup>2</sup>/sec) (mL O<sub>2</sub>) / (mL x mm Hg), and a substantially flexible peripheral hydrophilic portion coupled to the substantially rigid central portion at a junction defined at an outer edge of the substantially rigid central portion, wherein the junction comprises an angled surface, as recited in amended Claim 1.

Similarly, Domschke does not teach or suggest, alone or in combination with the cited references, a hybrid contact lens comprising a substantially rigid central portion having a DK value of at least  $30 \times 10^{-11}$  (cm<sup>2</sup>/sec) (mL O<sub>2</sub>) / (mL x mm Hg), and a substantially flexible peripheral hydrophilic portion coupled to the substantially rigid central portion at a junction defined at an outer edge of the substantially rigid central portion, a distance between an outer edge of the substantially flexible peripheral hydrophilic portion and the outer edge of the substantially rigid central portion being greater than 1 mm, wherein the junction comprises at least two intersecting planes, as recited in amended Claim 11.

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Likewise, Applicants respectfully submit, as noted above, that Domschke et al. does not teach or suggest, alone or in combination with the cited references, a hybrid contact lens comprising a substantially rigid central portion having a gas permeability value of at least  $30 \times 10^{-11}$  (cm<sup>2</sup>/sec) (mL O<sub>2</sub>)/ (mL x mm Hg), and a substantially flexible annular hydrophilic portion coupled to the substantially rigid central portion at a junction defined at an outer edge of the substantially rigid central portion, as recited in amended Claim 62

Applicants respectfully submit that the invention, as recited in the amended claims, is non-obvious in view of Domschke and Sohnges. Submitted herewith are the declarations of Dr. James Boucher, Dr. William Meyers, Dr. Joseph Barr, and Dr. Jerome Legerton, who together have over a century of experience in the contact lens and cornea fields. All agree that one of ordinary skill in the art would not combine Domschke et al. and Sohnges to result in the present invention.

Applicants respectfully submit that Domschke does not disclose a hybrid lens, as recited in amended Claims 1, 11 and 62. Instead, Domschke describes a polysiloxane-polyol macromer material, contact lenses including said material, and coating a surface of a lens with a hydrophilic material to improve the hydrophilicity of the lens. "Indeed, there is no disclosure or suggestion in Domschke to provide a hydrophilic peripheral skirt, or bond a hydrophilic peripheral skirt to a rigid central portion. Domschke's single reference to a hybrid lens appears to refer to either (a) a lens with a rigid core section and a hydrophilic surface, (b) a rigid gas permeable lens with very high flexure, or (c) a soft lens made of a Silicon Elastomer (aka Silicon rubber) with no water content, all of which have been referred to at times in the contact lens industry as hybrid lenses because they exhibited some characteristics found in both soft and rigid gas permeable lenses (e.g., intermediate rigidity between that of a rigid gas permeable lens and that of a soft lens). However, none of these contact lenses (i.e., a lens with a rigid core section and a hydrophilic surface, a rigid gas permeable lens with very high flexure, or a soft lens with no water content) teach or suggest a contact lens having a substantially rigid central portion coupled to a substantially flexible hydrophilic peripheral portion, as recited in the amended claims of the above-identified application." Legerton Declaration, Paragraph 10; Barr Declaration, Paragraph 10, Boucher Declaration, Paragraph 12; Meyers Declaration, Paragraph 10.

Sohnges does not disclose a hybrid contact lens having a hard central portion with a DK of at least  $30 \times 10^{-11}$  (cm<sup>2</sup>/sec) (mL O<sub>2</sub>)/ (mL x mm Hg). "In fact, this patent does not even

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disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear pumping or movement under the lens.” Legerton Declaration, Paragraph 11; Barr Declaration, Paragraph 11, Boucher Declaration, Paragraph 13; Meyers Declaration, Paragraph 11.

Additionally, Sohnges teaches away from using a hydrophilic skirt and the materials identified in Sohnges are not hydrophilic. See Sohnges, page 1, lines 49-53. Indeed, “there is no disclosure or suggestion in Sohnges to 1) provide a hybrid contact lens with a high DK central portion, 2) provide a hydrophilic skirt, or 3) bonding a high DK central portion to a hydrophilic skirt in any manner.” Legerton Declaration, Paragraph 11; Barr Declaration, Paragraph 11, Boucher Declaration, Paragraph 13; Meyers Declaration, Paragraph 11.

Accordingly, modification of the contact lens disclosed in Sohnges using the material of Domschke et al. would fail to produce the claimed invention. See Legerton Declaration, Paragraph 11; Barr Declaration, Paragraph 11, Boucher Declaration, Paragraph 13; Meyers Declaration, Paragraph 11.

Additionally, there has been a long felt but unsolved need for a hybrid contact lens having a substantially rigid portion with a DK greater than  $30 \times 10^{-11}$  (cm<sup>2</sup>/sec) (mL O<sub>2</sub>)/ (mL x mm Hg), and a substantially flexible hydrophilic portion coupled to the substantially rigid portion. See Legerton Declaration, Paragraph 13; Barr Declaration, Paragraph 13, Boucher Declaration, Paragraph 15; Meyers Declaration, Paragraph 13.

In view of the foregoing, Applicants respectfully submit that amended Claims 1, 11 and 62 are patentable over Domschke et al., alone or in combination with the cited references. Claims 2-10 and 51 depend from Claim 1, and would likewise be patentable over Domschke et al., alone or in combination with the cited references, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught or suggested by the cited art. Similarly, Claims 44-50 depend from amended Claim 11, and would therefore likewise be patentable over Domschke et al., alone or combination with the cited references, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught or suggested by the cited art. Claims 65, 66, 70 and 71 depend from amended Claim 62, and would therefore likewise be patentable over Domschke et al., alone or combination with the cited

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references, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught or suggested by the cited art.

New Claims

Applicants have added new dependent Claims 72 and 73, which depend from amended Claims 62 and 11, respectively. In view of the arguments above, Applicants respectfully submit that new Claims 72 and 73 are likewise patentable over Domschke et al. in combination with Sohnges, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught or suggested by the cited art.

CONCLUSION

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

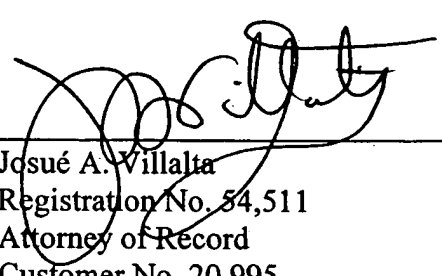
Respectfully submitted,

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Dated: \_\_\_\_\_

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By: \_\_\_\_\_

  
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